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DEPARTMENT OF JUSTICE

Drug Enforcemnt Administration

[Docket No. 12-43]

MARK G. MEDINNUS, D.D.S. DECISION AND ORDER

On October 17, 2012, Administrative Law Judge (ALJ) Gail A. Randall issued the attached Recommended Decision (hereinafter, cited as R.D.¹). The Government filed Exceptions to the Recommended Decision.

Having reviewed the record in its entirety, I reject the Government's Exceptions and adopt the ALJ's findings of fact and conclusions of law except as discussed below. I also adopt in part, and reject in part, the ALJ's recommended order. A discussion of the Government's Exceptions follows.

THE GOVERNMENT'S EXCEPTIONS

The Unauthorized Purchase Allegation

The Government first takes exception to the ALJ's finding that it failed to prove that Respondent, while serving as the dental director of the Round Valley Indian Health Clinic (RVIHC), made an unauthorized purchase of two controlled substances (hydrocodone and codeine). Exceptions at 2. The contention is not well taken as either a factual or legal matter.

The evidence showed that on November 29, 2010, Respondent prepared a purchase order for various dental supplies, including one bottle of 500 tablets of hydrocodone/acetaminophen and one bottle of 500 tablets of codeine/acetaminophen. GX 10, at 1-3; Tr. 151. The purchase order comprised all of one page and listed a total of eleven items; the order was approved by Jan

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¹ All citations to the R.D. are to the ALJ's slip opinion.

Scribner, the deputy director of the RVIHC. <u>Id.</u>; Tr. 158._The evidence further showed that Ms. Scribner had authority to approve purchase orders in the absence of the RVIHC's executive director. GX 21.

In challenging this finding, the Government takes issue with the ALJ's credibility findings. Citing Ryan v. CFTC, 145 F.3d 910, 918 (7th Cir. 1998), it argues that I am "free to discount the weight that the ALJ placed on the testimony when the record would support an alternative finding." Exceptions at 1 (also citing <u>Universal Camera Corp. v. NLRB</u>, 340 U.S. 474 (1951)).²

More specifically, the Government requests that I reject the ALJ's credibility findings regarding the testimony of both Respondent (whom she found credible on the issue of whether a dental clinic employee had told him that the executive director had approved the purchase order, see R.D. at 12, 27) and the clinic employee (whom she found not credible when she testified that the executive director did not think it was a good idea because of Respondent's history of substance abuse, see id.). See Exceptions at 2-6. While the Government clearly misreads Ryan, I conclude that it is not necessary to either adopt or reject the ALJ's credibility findings,

² In the Show Cause Order, the Government alleged both that Respondent made an unauthorized purchase of controlled substances, and that he stored and dispensed controlled substances at the RVIHC's dental clinic in violation of the RVIHC's guidelines for storing and dispensing controlled substances. ALJ Ex. 1, at 2. The ALJ reasoned that because Respondent "reasonably believed the purchase order was duly approved, the Government's allegation that he failed to abide by RVIHC policies regarding the storage and dispensing of controlled substances, also fails." R.D. at 28. It is, however, far from clear why, even if Respondent had authority to order controlled substances, this would necessarily lead to the conclusion that he also had authority to store and dispense controlled substances out of the dental clinic.

In taking exception to the ALJ's findings regarding the purchase, the Government also takes issue with the ALJ's finding that Respondent "honestly and reasonably believed he possessed the necessary authority to store and dispense controlled substances in [the RVIHC] dental department." Exceptions at 2. To the extent the Government has even properly put this finding at issue, I reject its contention, because, by itself, it does not establish a violation of the CSA or state law, or otherwise actionable misconduct under the public interest standard.

³ At issue in <u>Ryan</u> was whether an Agency was required to defer to an ALJ's finding that an applicant for a trader's license "was fully rehabilitated and not a threat to the integrity of the [commodities] markets," which was based on the ALJ having found credible the testimony of the applicant's character witnesses. <u>See</u> 145 F.3d at 918. The Commission discredited the testimony because "almost every one can produce" a character witness who will testify

because even were I to reject the findings with respect to both Respondent and the clinic employee, the Government cannot overcome the evidence that the purchase order was approved by an official of the clinic, who indisputably had authority to do so. R.D. at 12, 27; Tr. 158.

The Government attempts to overcome this evidence, arguing that in an affidavit, the deputy director "unequivocally states that she was not aware [that] the purchase order, which contained a number of items, also contained an order for controlled substances." Exceptions at 7. The Government then argues that "[a] review of the purchase order shows that . . . the controlled substances order is buried in the middle/end of the purchase order." Id.

The Government's argument is wholly unpersuasive. Notably, the purchase order was but a single page in length and listed all of eleven items. GX 10, at 1. Moreover, the purchase order clearly described the respective controlled substances as "1 bottle" of "Hydrocodone" and "1 bottle" of "APAP w/codeine." Id. Thus, even a cursory review of the purchase order by the deputy director should have revealed that it contained controlled substances. I thus give no weight to the assertion of the deputy director that she inadvertently approved the order and reject the Government's contention that Respondent's purchase of controlled substances was

as to his/her "belief that the defendant will not repeat his violative conduct," and because the "testimony reflected at most a perfunctory concern with the customers harmed by Ryan's wrongdoing." <u>Id</u>. (internal citation omitted).

The Seventh Circuit held that the Commission could "discredit the weight of a witness's testimony without impinging on an ALJ's credibility determinations." <u>Id.</u> As the court of appeals further explained:

The Commission must attribute significant weight to an ALJ's findings based on a witness's demeanor because it does not have the opportunity to observe a testifying witness. This recognition, however, does not preclude the Commission from discounting the weight that an ALJ places on witness's testimony when the Commission questions the witness's basis of knowledge.

<u>Id</u>. In short, <u>Ryan</u> provides no support for the Government's contention, which ignores that the ALJ's finding involves an issue of historical fact and involves a classic situation in which an assessment of each witness's demeanor is essential in making a factual finding.

unauthorized.⁴ Cf. Consolidated Edison Co. v. United States, 221 F.3d 364, 371 (2d Cir. 2000) ("In general, individuals are charged with knowledge of the contents of documents they sign - that is, they have 'constructive knowledge' of those contents.").⁵

Even if the Government's contention was supported by substantial evidence, I would nonetheless reject the exception. Notably, while the Government argues – as an afterthought – that Respondent used the clinic's "DEA registration without authorization from RVIHC executive personnel," it does not go so far as to maintain that this constitutes a violation of the Controlled Substances Act. See Exceptions at 10, but see 21 U.S.C. § 843(a)(2) ("It shall be unlawful for any person knowingly or intentionally . . . to use for the purpose of acquiring or obtaining a controlled substance, a registration number which is . . . issued to another person."). Indeed, notwithstanding that Respondent could not account for forty tablets of hydrocodone, the evidence showed that the drugs were generally dispensed to patients in the course of providing dental treatment. Finally, while in its post-hearing brief, the Government notes that both factors four (compliance with applicable controlled substance laws, 21 U.S.C. § 823(f)(4)) and five (such other conduct which may threaten public health and safety, id. § 823(f)(5)), are to be considered in determining the public interest, it does not cite to any provision of state law that

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⁴ In her affidavit, the Deputy Director also stated that "RVIHC does not order controlled substances from Henry Schein," that it "orders all controlled substances from other government suppliers by RVIHC contracts with those venders [sic]," and that "[t]his procedure has been long standing and well known to all relevant staff." GX 21, at 1. The Government, however, produced no evidence that these purported procedures have been memorialized in writing. Nor did the Government establish that Respondent was aware of any such policy. Beyond this, the Deputy Director's assertion that the procedure is well known undermines any claim that she is a disinterested witness, which, given that her testimony constitutes hearsay, is a relevant consideration in determining the reliability of her statement.

⁵Given that the purchase order was but a single page, listed only eleven items, and clearly listed hydrocodone and codeine as among the items to be purchased, <u>see GX</u> 10, it is fair to draw the inference that the Deputy Director had actual knowledge that Respondent was seeking controlled substances.

Respondent violated in making the purported unauthorized purchase.⁶ Nor does it cite to any Agency decision holding that a violation of a clinic's internal operating policies, which does not otherwise violate the CSA or state law, constitutes conduct "inconsistent with the public interest." 21 U.S.C. § 824(a)(4). Thus, even if the Government had proved that Respondent made an unauthorized purchase of the two drugs, I would reject the exception because it fails to establish actionable misconduct under the public interest standard.

The ALJ's Finding that Respondent Has Accepted Responsibility

The ALJ found that Respondent took responsibility for his actions and "repeatedly demonstrated remorse for his conduct at the RVIHC." R.D. at 29. The Government takes exception to this finding, arguing that while Respondent acknowledged the misconduct he committed prior to 2008, he "was not candid and not willing to accept actual responsibility for his [more recent] violations," which included his "inaccurate dispensing records, the unlawful dispensing to an unknown patient, and the failure to keep a dispensing log as required by" the probation imposed by the Dental Board of California when it issued him a new license. Exceptions at 8 (emphasis added).

Respondent is, however, only required to accept responsibility for the misconduct which the Government has proven on the record. See Jeffrey P. Gunderson, 61 FR 26208, 26211 (1996) (a respondent must "admit to the full extent of his involvement in documented misconduct"). With respect to the alleged "unlawful dispensing to an unknown patient," Exceptions at 8, the Government points to evidence that Respondent "dispensed hydrocodone to a transient without eve [sic] documenting that he ever saw this person as a patient at the time he

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⁶ Indeed, in its brief containing its proposed findings of fact and conclusions of law, the only provisions of law or regulations cited by the Government are various recordkeeping requirements, which it is undisputed that Respondent violated. Gov't Prop. Findings of Fact, Conclusions of Law, and Argument (hereinafter, Gov't Post-Hrng. Br.) at 19 (citing 21 U.S.C. § 827(a)(3); 21 CFR 1304.22(c)).

dispensed the Vicodin." Gov't Post-Hrng. Br. at 23. The Government argues that "[t]his incident is not just a 'documentation' error but is tantamount to outright diversion." <u>Id</u>. Yet, the ALJ found that Respondent "credibly testified that he had examined the patient on January 20, 2011, and observed that he needed a surgical extraction," that "[w]hen the patient returned to [the clinic] on January 24, 2011, [Respondent] could not perform the extraction because of his busy schedule," and that "[w]hen the patient reported experiencing pain symptoms, [he] agreed to provide him with hydrocodone to temporarily alleviate his symptoms." R.D. at 14.

The Government did not, however, take exception to these findings. Thus, while in its post-hearing brief, the Government argued that Respondent engaged in "outright diversion" when he provided hydrocodone to this patient, and in its Exceptions, it argues that he has failed to accept responsibility for the "unlawful dispensing," I conclude that Government has offered no reason to reject the ALJ's findings. Moreover, Respondent acknowledged that he failed to properly document the dispensing. Tr. 523. Because Respondent accepted responsibility with respect to the only misconduct the Government proved with respect to this patient, I reject the Government's contention to the extent it relies on Respondent's act of dispensing a controlled substance to this patient.

The record, however, does establish that Respondent failed to maintain accurate dispensing records, as well as a dispensing log, which was required under the terms of the Dental Board's order, which restored his dental license. While there is some evidence to support the Government's contention that Respondent did not accept responsibility for his failure to maintain accurate records, I conclude that the ALJ's finding is supported by the record as a whole.

⁷ Nor did the Government offer any evidence at the hearing as to the standards of dental practice and establishing that Respondent acted outside of the usual course of professional practice when he dispensed hydrocodone to this patient. See 21 CFR 1306.04(a).

At the hearing, Government counsel asked Respondent whether it was correct that he did not keep "a separate dispensing record when [he] started to use the Vicodin . . . that [he] had ordered." Tr. 491. Respondent answered that this was "[a]bsolutely correct." Id. When asked by the Government whether he had "the legal duty to keep accurate records of th[e] Vicodin supply," Respondent answered: "I do." Id. at 498. And when asked whether it was correct that because he "had the supply, . . . did the dispensing directly to the patients, . . . [he] had the obligations to keep an accurate patient chart as well as a log," Respondent answered: "Absolutely. That's why I say I didn't do it right." Id. at 499.

Subsequently, the Government asked Respondent whether "hav[ing] shortages and . . . overages" is "a violation of DEA law?" <u>Id</u>. at 509. Respondent answered that he knew that he had violated the State Board's order but that he did not know if this was a violation of federal law. <u>Id</u>. The Government then asked Respondent if it was "a violation of DEA law not to keep a separate dispensing log for narcotic controlled substances?" <u>Id</u>. at 509-10. Respondent answered:

I don't know, but I do know that I violated [the State] order. I'm willing to stipulate that I violated that too. However you want to characterize it, they wouldn't have happened if I hadn't made my mistakes. There would be no three separate logs. So if you want to say that I violated a couple of steps, of course, I'm willing to stipulate that there was a tough time in my life. I'm sorry. I don't mean, if I get argumentative, I ask the Court's forgiveness.

Id.

Respondent also testified that he had abused the public trust in his handling of Vicodin while at the RVIHC. Tr. 539-40. While Respondent subsequently testified that there was a difference in degree between his previous violations and the violations he committed at RVIHC, he testified that "I abused the public trust here" and "I screwed up." <u>Id</u>. And while his closing

statement is not technically evidence, therein, Respondent stated: "I'm sorry that I made the mistakes in the past and then more recently." <u>Id</u>. at 554.

Ignoring nearly all of the evidence which supports the ALJ's finding, the Government argues that "Respondent repeatedly minimized the significance of his dispensing-record violations." Exceptions at 10. As support for this contention, it quotes Respondent's testimony that "we're talking about 40 tabs. . . . so I'm going to jeopardize my licenses for 40 Vicodin tabs . . . [f]or forty tabs?" Respondent did not, however, offer this testimony to downplay the dispensing record violations but rather to respond to the insinuation (which permeates the proceeding but which is unproven on the record) that he had resumed self-abusing controlled substances. Accordingly, I reject the Government's contention that Respondent has failed to accept responsibility for his misconduct.

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⁸ The Government points to several other portions of Respondent's testimony which it asserts provide evidence that he has not admitted to his misconduct. <u>See Exceptions at 8-9</u>. As support for these assertions, the Government did not cite to the specific pages of the transcript or exhibits, as is required by DEA's regulation, <u>see 21 CFR 1316.66(a)</u>, but to a document which is abbreviated as "FCA." <u>Id.</u> Nowhere in its Exceptions does the Government identify what this term means, and while it may be a reference to the Government's proposed findings of fact, conclusion of law, and argument, the Agency has previously held that citation to a post-hearing brief does not comply with the regulation and is ground to reject an exception. <u>See Carlos Gonzales</u>, 76 FR 63118, 63119 (2011).

In any event, I have considered the entirety of Respondent's testimony in reviewing the ALJ's finding and conclude that much of the testimony cited by the Government is not probative of whether he has accepted responsibility for his failure to maintain accurate records. For example, the Government contends that "Respondent did not admit to wrongdoing when he was asked during cross-examination whether the audit shortages could be partially attributable to the hydrocodone he gave to the transient patient." Exceptions at 9. A review of what appears to be the relevant portion of the transcript shows that the Government asked Respondent whether the forty dosage unit shortage "could be accounted for, if not in total, at least in part based on the amount of Vicodin that [he] dispensed to [the] transient that did not get charted." Tr. 528. Respondent answered: "I suppose some of the Vicodin, some of those 40 tabs could have been it. I don't know. I'm confused. Do you want me to confess to something?" Id. The Government offers no further explanation as to why this testimony supports rejection of the ALJ's finding.

The Government also points to a question it asked Respondent about an e-mail to the RVIHC Executive Director, in which he wrote that he "desperately wanted to be liked by the natives so I prescribed Vicodin too liberally." Exceptions at 9; see also Tr. 506. When asked whether this was "a true statement," Respondent answered: "No, I was being disingenuous." Tr. 506. While this answer does not inspire confidence in Respondent's credibility, the Government neither alleged, nor established that he acted outside of the usual course of professional practice and lacked a legitimate medical purpose with respect to any of the dispensings he made to the clinic's patients, and by itself, the testimony is insufficient to support rejection of the ALJ's credibility findings.

However, while I adopt the ALJ's finding that Respondent has accepted responsibility for his misconduct, I nonetheless conclude that the ALJ's proposed sanction does not adequately protect the public interest. As noted above, pursuant to the Dental Board's order which restored his dental license, Respondent was required to "maintain a record of all controlled substances prescribed, dispensed or administered by [him] during probation." GX 7, at 7. This record was required to be maintained "in a separate file or ledger," and to include, "in chronological order," each patient's name and address, the date, the controlled substances and quantity, and "the pathology and purpose for which the controlled substance was furnished." Id. Moreover, under federal law, Respondent was required to maintain a complete and accurate record of all controlled substances he dispensed. 21 U.S.C. § 827(a)(3); 21 CFR 1304.22(c).

Notwithstanding the egregiousness of his prior misconduct, Respondent did not appreciate the forbearance shown by the Board⁹ and this Agency in granting him a second chance. Accordingly, while Respondent's application will be granted, his registration will be subject to the following conditions:

1. Upon the granting of Respondent's application, his registration will be suspended outright for a period of six months. Thereafter, Respondent's registration will be suspended through the expiration of his registration; however, this portion of the suspension shall be stayed provided Respondent fully complies with the conditions

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⁹ As the ALJ found, Respondent has a history of substance abuse and in February 2003, pled guilty to one felony count of obtaining controlled substances by fraud in violation of Cal. Health & Safety Code § 11173(a). R.D. at 8. While upon Respondent's successful completion of his probation, the conviction was reduced to a misdemeanor and then dismissed entirely, the record shows that Respondent unlawfully obtained approximately 30,000 dosage units of controlled substances. GX 3; GX 4, at 4-5; GX 5, at 2.

Based on this misconduct, in September 2002, the Dental Board of California (DBC) filed an accusation against Respondent and he surrendered his state dental license. GX 5. On May 26, 2006, Respondent filed a petition to reinstate his dental license; on June 12, 2007, the DBC granted the petition. GX 7.

imposed on his registration, the conditions of any existing or future Dental Board order which relate to the use or handling of controlled substances, as well as all federal and state controlled-substance laws and regulations.

- 2. Respondent is prohibited from administering or dispensing directly controlled substances. Respondent is authorized only to prescribe controlled substances.
- 3. Respondent is required to maintain a log, in chronological order, of all controlled-substance prescriptions he issues. The log must include the following information:

 1) the date; 2) the patient's name and address; 3) the drug name, its strength, and quantity; and 4) the pathology and purpose of the prescription. Respondent shall maintain the log at his registered address. In addition, Respondent must provide a copy of the log to the nearest DEA field division office, on a quarterly basis, within seven calendar days of the last day of each quarter ending on March 31st, June 30th, September 30th, and December 31st.
- 4. Respondent shall not prescribe any controlled substance to himself or a family member.
- 5. Respondent is required to notify the nearest DEA field division office within 72 hours of any violation of this Order, any Dental Board Order, or any provision of federal or state law related to controlled substances.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. § 823(f), as well as 28 CFR 0.100(b), I order that the application of Mark G. Medinnus, D.D.S., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, granted, subject to the conditions set forth above. This

Order is effective [Insert Date]	Thirty Days from the	Date of Publication in	n the Federal
Register].			

Dated: September 22, 2013 Michele M. Leonhart

Administrator

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

I. PROCEDURAL BACKGROUND

Gail A. Randall, Administrative Law Judge. The Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration ("DEA" or "Government"), issued an Order to Show Cause ("Order" or "OSC") dated March 22, 2012, proposing to deny the application of Mark G. Medinnus, D.D.S. ("Respondent" or "Dr. Medinnus") for a DEA Certificate of Registration pursuant to 21 U.S.C. § 824(a)(2)–(4) and § 823(f)(2)–(5), because the registration of the Respondent would be inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f). [Administrative Law Judge Exhibit ("ALJ Exh.") 1 at 1].

The Order stated that Respondent had been previously registered with the DEA as a practitioner with authority to handle controlled substances in Schedules II-IV under DEA Certificate of Registration BM0207678. [Id.]. The Order stated that Respondent had voluntarily surrendered this registration on January 16, 2002. [Id.].

The Order further stated that on July 30, 2008, Respondent had been granted a DEA Certificate of Registration FM0982808 as a practitioner with authority to handle controlled substances in Schedules II-IV. [Id.]. The Order stated that this registration expired without a timely renewal on January 31, 2011. [Id.].

The Order also stated that on December 18, 2002, Respondent entered into a Stipulated Surrender of License and Order with the Dental Board of California wherein Dr. Medinnus surrendered his rights and privileges as a dentist in the state of California. [Id.]. The Order went on to state that on June 12, 2007, Respondent's dental license was reinstated subject to

probationary conditions for a period of five years, including that he maintain a controlled substance dispensing log in chronological order. [<u>Id.</u> at 2]. The Order alleged that Respondent failed to maintain this required dispensing log. [<u>Id.</u>].

The Order also stated that on February 23, 2003, Respondent pled guilty to a felony violation of CAL. HEALTH & SAFETY CODE § 11173(a) (West 2012) for obtaining controlled substances by fraud. [Id.]. The Order stated that the basis of this conviction was Respondent's use of DEA Certificate of Registration BM0207678 to divert more than 30,000 dosage units of hydrocodone, lorazepam, and diazepam for his personal use from approximately January 2000 through November 2001. [Id.].

Lastly, the Order alleged that in December 2010, while Respondent was an employee of the Round Valley Indian Health Center ("RVIHC"), Dr. Medinnus made an unauthorized purchase of bottles of hydrocodone and codeine using RVIHC's DEA registration. [Id.]. In addition, the Order alleged that in January 2011, Respondent failed to comply with RVIHC's guidelines regarding the storage and dispensing of controlled substances and that Respondent could not account for approximately sixty-eight tablets of hydrocodone/apap which he allegedly dispensed. [Id.]. The Deputy Assistant Administrator then gave the Respondent the opportunity to show cause as to why his application should not be denied on the basis of these allegations. [Id.].

On April 5, 2012, Respondent timely filed a request for a hearing in the above-captioned matter. [ALJ Exh. 2].

After authorized delays, the hearing was conducted on July 10-11, 2012, in Sacramento, California. [ALJ Exh. 5]. At the hearing, counsel for the DEA called four witnesses to testify

and introduced documentary evidence. [Transcript ("Tr.") Volume I-II]. The Respondent called two witnesses to testify, including himself, and introduced documentary evidence. [Id.].

After the hearing, the Government and the Respondent submitted Proposed Findings of Fact, Conclusions of Law and Argument ("Govt. Brief" and "Resp. Brief").

II. ISSUE

The issue in this proceeding is whether or not the record as a whole establishes by a preponderance of the evidence that the Drug Enforcement Administration should deny the application for a DEA Certificate of Registration of Mark G. Medinnus, D.D.S.as a practitioner, pursuant to 21 U.S.C. § 824(a)(2)-(4) (2006), and pursuant to 21 U.S.C. § 823(f)(2)-(5), because the Respondent's registration would be inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f). [ALJ Exh. 4; Tr. 7].

III. FINDINGS OF FACT

A. Stipulated Facts

- On September 19, 2011, Dr. Medinnus applied for registration with DEA as a practitioner in Schedules II through V at 9024 Sniktaw Lane, Fort Jones, CA 96032.
- Dr. Medinnus was previously registered with DEA as a practitioner in Schedules II
 through IV under DEA Certificate of Registration BM0207678 at 1680 Westwood Drive,
 Suite C, San Jose, CA 95125. Dr. Medinnus voluntarily surrendered this registration on
 January 16, 2002.
- On July 30, 2008, Dr. Medinnus was granted DEA Certificate of Registration
 FM0982808 as a practitioner, in Schedules II through IV, at P.O. Box 459, Lewiston,
 CA, 96052. This registration expired without a timely renewal on January 31, 2011.

- 4. On September 3, 2002, the Dental Board of California, Department of Consumer Affairs, (hereinafter "Dental Board") issued an "Accusation" which sought to revoke or suspend Dr. Medinnus' dental license. The "Accusation" alleged that Dr. Medinnus ordered controlled substances in order for his own and others illegal use and not in the course of his dental practice.
- 5. On September 20, 2002, Dr. Medinnus entered into a "Stipulated Surrender of License and Order" with the Dental Board as a result of the September 3, 2002, Dental Board "Accusation." In the September 20, 2002, "Stipulated Surrender of License and Order," Dr. Medinnus agreed to surrender his California dental license.
- Effective December 18, 2002, the Dental Board adopted the September 20, 2002,
 "Stipulated Surrender of License and Order."
- 7. On February 27, 2003, Dr. Medinnus pled guilty in Santa Clara County to one felony count of a violation of California Health & Safety Code 11173, obtaining controlled substances by fraud. Dr. Medinnus was sentenced to probation.
- 8. On April 27, 2006, Dr. Medinnus' felony conviction of California Health & Safety Code 11173 was reduced to a misdemeanor conviction under California Penal Code, Section 17, and then the conviction was dismissed under California Penal Code, Section 1203.4.
- 9. On or about May 26, 2006, Dr. Medinnus petitioned the Dental Board to re-instate his license. On March 15, 2007, a Dental Board Administrative Law Judge submitted a "Proposed Decision" to grant Dr. Medinnus' petition to re-instate his dental license subject to probation for five years. The "Proposed Decision" was adopted by the Dental Board in a "Decision" on May 10, 2007. The "Decision" became effective on June 12, 2007.

- 10. Hydrocodone, in combination dosage unit form, is a Schedule III narcotic controlled substance. Its brands, inter alia, include Lortab, Lorcet and Vicodin.
- 11. Codeine with apap, in dosage unit form, is a Schedule III narcotic controlled substance.
- 12. Lorazepam and diazepam are both Schedule IV depressant controlled substances.
- 13. The Respondent stipulates that the Government can establish a <u>prima facie</u> case supporting the denial of his pending DEA Certificate of Registration application. [ALJ Exh. 6].

B. Respondent's Registration History

The Respondent was first licensed to practice dentistry in 1985. [Govt. Exh. 5]. On November 25, 1985, the Agency issued a Certificate of Registration Number BM0207678 to Respondent as a practitioner with authority to handle controlled substances in schedules II-IV. [Govt. Exh. 2; Tr. 323]. Respondent voluntarily surrendered this registration for cause on January 18, 2002. [Govt. Exh. 2; Tr. 323-24].

On July 23, 2008, Respondent applied for a new DEA Certificate of Registration. [Tr. 326]. This application was granted and the Agency issued Certificate of Registration Number FM0982808 to Respondent as a practitioner with authority to handle controlled substances in schedules II-IV. [Govt. Exh. 3; Resp. Exh. A74; Tr. 325-326]. This registration expired on January 31, 2011 and was retired from the DEA computer system on December 5, 2011. [Govt. Exh. 3].

On September 19, 2011, Respondent submitted a new application for registration under DEA control number W11065544C. [Govt. Exh. 1; Tr. 321]. This application is the subject of these proceedings. [Id.].

C. Respondent's Addiction History

Respondent began experiencing headaches and tinnitus in approximately 1996 while he was working in a private family dentistry practice in San Jose, California. [Govt. Exh. 7 at 2]. To treat these conditions, Dr. Medinnus began to take Vicodin tablets from his office. [Id.]. By 1999, Respondent was addicted to Vicodin and he had begun to supply his family members with Vicodin for non-dental medical conditions. [Id.]. Respondent's headaches were eventually diagnosed as resulting from cataracts, and he underwent surgery. [Id.]. During his recovery from surgery and while suffering from depression, Respondent closed his dental practice in June 2000. [Id.]. Despite the closure of his practice, Dr. Medinnus continued to order large quantities of controlled substances to support his addiction and provide pills for his family members from approximately 2000 to 2001. [Id.; Tr. 426-427]. When confronted by a Dental Board of California ("DBC" or "the Board") investigator in January 2002 regarding these orders, Respondent admitted to illegally obtaining these controlled substances and using them to support his addiction. [Govt. Exh. 7 at 2]. Dr. Medinnus voluntarily surrendered his DEA registration on January 18, 2002 by signing a DEA Form 104. [Tr. 323].

D. 2002 DBC Action Against Respondent

On September 3, 2002, the Dental Board of California ("DBC" or "the Board") filed an accusation against Respondent seeking to suspend or revoke his California dental license. [Govt. Exh. 4; Tr. 327]. Therein, the DBC alleged that Respondent had ordered significant quantities of controlled substances, including hydrocodone, lorazepam, and diazepam, from approximately January 2000 to November 2001, for his own personal use and to unlawfully distribute to others. [Govt. Exh. 4 at 3-5]. Respondent entered into a Stipulated Surrender of License and Order with the Board on September 20, 2002, wherein he admitted to the allegations contained in the DBC's

accusation and surrendered his dental license to the Board. [Govt. Exh. 5; Tr. 328]. On November 18, 2002, the Board adopted the Stipulated Surrender of License and Order in a Decision and Order which became effective on December 18, 2002. [Govt. Exh. 6; Tr. 329].

E. Respondent's 2003 Felony Conviction and Subsequent Exclusion from Medicare

On February 27, 2003, Dr. Medinnus pled guilty in Santa Clara County, California to one felony count of a violation of CAL. HEALTH & SAFETY CODE § 11173(a) (West 2012) for obtaining controlled substances by fraud. [Resp. Exh. 3]. Dr. Medinnus was sentenced to three years' probation. [Govt. Exh. 7 at 2]. Respondent successfully complied with all his probationary conditions and on April 27, 2006, Dr. Medinnus successfully petitioned to reduce his felony conviction to a misdemeanor pursuant to CAL. PENAL CODE § 17(b)(3) (West 2012) and then dismissed pursuant to CAL. PENAL CODE § 1203.4(a) (West 2012). [Resp. Exh. A-17; Tr. 350-351].

Pursuant to this felony conviction, the Department of Health and Human Services ("HHS") excluded Dr. Medinnus from participating as a healthcare provider in Medicare for a period of five years. [Resp. Exh. A86]. In addition, on June 23, 2004, the Office of Personnel Management ("OPM") debarred Respondent from participating in the Federal Employees Health Benefits Program. [Resp. Exh. A87]. On April 20, 2009, HHS reinstated Respondent's eligibility to participate as a Medicare provider and OPM terminated Respondent's debarment from the Federal Employees Health Benefits Program. [Resp. Exh. A86-87; Tr. 356-357].

F. Respondent's Rehabilitation Program and Dental License Reinstatement

Following Respondent's felony conviction, he began an intensive drug rehabilitation program. [Govt. Exh. 7 at 2-3]. This program included attending individual and group therapy sessions with a licensed therapist to address Respondent's mental health and substance abuse

issues. [Resp. Exh. A5-8]. In addition, Respondent received psychiatric treatment, including medication, to treat his symptoms of depression. [Resp. Exh. A13-15]. Respondent also participated in frequent twelve-step program meetings and joined the board of a local transitional housing facility for recovering addicts. [Resp. Exh. A3-4; A9-11].

On May 26, 2006, Respondent filed a petition for reinstatement of his California dental license. [Govt. Exh. 7 at 2]. As part of his petition, Dr. Medinnus submitted letters of recommendations from fellow dentists regarding his clinical abilities. [Resp. Exh. A32-34]. Respondent also proffered evidence regarding his family life, involvement in his stepchildren's elementary school and athletics programs and his own volunteer activities. [Resp. Exh. A19, A21, A25, A26-27, A30-31, A91]. After an administrative hearing, a state administrative law judge recommended that the DBC reinstate Respondent's dental license and place the Respondent on probation for a period of five years. [Govt. Exh. 7 at 5; Tr. 292-293]. The ALJ made detailed factual findings regarding Dr. Medinnus' successful drug rehabilitation program. [Govt. Exh. 7 at 3-4]. These included maintaining his sobriety from March 7, 2003, receiving outpatient medical and psychotherapy treatment, attending NA and AA meetings, and completing continuing dental education courses. [Id.]. The ALJ further found that Respondent had complied with all the terms of his criminal probation, recovered completely from his cataract surgery, and had credibly addressed the triggers that led to his drug addiction and diversion to his family members. [Id.].

The ALJ recommended that Respondent's dental license be subject to several probationary conditions, including that he maintain a separate log of all controlled substances that he prescribed, dispensed or administered during his probationary period. [Govt. Exh. 7 at 7; 293-294]. Among other conditions, Dr. Medinnus was also required to pass a dental licensing

examination, undergo a psychiatric evaluation, participate in a diversion program offered by the Board, and be subject to random drug screenings. [Govt. Exh. 7 at 5-9]. On May 10, 2007, the Board adopted the ALJ's Decision, which became effective on June 12, 2007. [Govt. Exh. 8; Tr. 330-331].

To regain his probationary dental license, Dr. Medinnus successfully completed the mandated dental licensing examination on July 14, 2007. [Resp. Exh. A61; A85]. Respondent also received a comprehensive psychiatric evaluation, which favorably reported his ongoing recovery. [Resp. Exh. A57]. In addition, on December 6, 2007, Respondent was released from the Board mandated diversion program. [Resp. Exh. A58; Resp. Exh. 6]. During this time, Dr. Medinnus took and passed numerous random drug screens as directed by the DBC. [Resp. Exh. A45-47; A49; A51; A53-54]. When his probationary dental license was issued, Dr. Medinnus performed volunteer dental consulting work at Milestones Health Center in Weaverville, California. [Resp. Exh. A68; A76].

G. Respondent's Employment at RVIHC

After the reinstatement of his dental license, Respondent negotiated an employment contract to work as the dental director at the Round Valley Indian Health Center, ("RVIHC") which is located in Covelo, California. [Govt. Exh. 9; Tr. 31]. One of the terms of the employment contract was that the Respondent agreed to "comply with all policies and procedures, rules and regulations of the RVIHC funding agencies and federal and state laws including all of the HIPPA requirements." [Govt. Exh. 9 at 2].

James Russ, the executive director of RVIHC, testified at the hearing, and I find his testimony credible and consistent with the documentary evidence. Mr. Russ testified that prior to the negotiation of his contract, Dr. Medinnus voluntarily and freely disclosed his history of

substance abuse and the surrender of his dental license and DEA registration in 2002 and its subsequent reinstatement. [Tr. 34-35].

As RVIHC's executive director, Mr. Russ administers the day-to-day operations of the clinic's various departments. [Tr. 23-24]. Mr. Russ outlined RVIHC's operation and the services it provided including operating a medical center, dental clinic, outpatient physical or psychological treatment, and a group home. [Tr. 24-25]. He testified that all controlled substances ordered by RVIHC were stored in a central dispensary, which contained a locked safe. [Tr. 25-26]. Mr. Russ further testified that RVIHC's usual suppliers of controlled substances were McKesson and Pharmadex, and did not include Henry Schein, a supplier from whom RVIHC only ordered dental supplies. [Tr. 40-41].

Linda Lohne, a registered nurse and clinic manager at RVIHC, also testified at the hearing. [Tr. 186]. I find her testimony credible and consistent with the documentary evidence. As part of her clinic manager duties, Ms. Lohne oversaw RVIHC's ordering and dispensing of controlled substances. [Tr. 187]. She likewise testified that all controlled substances ordered under RVIHC's DEA registration were stored in the clinic's central dispensary. [Id.].

Mr. Russ testified that Dr. Medinnus had discussed with him the possibility of storing hydrocodone in the dental department to obviate the need for Respondent or his dental staff to pick up the controlled substances at the dispensary and then return to the dental department to dispense them to the patients. [Tr. 51, 90; Resp. Exh. A134-135, A148]. Mr. Russ discussed his concerns about this request with Respondent, including his belief that the controlled substances would be more secure if they remained in the central dispensary. [Tr. 70-71].

Dr. Medinnus testified that he sought to order controlled substances to store in the dental department because the dispensary would occasionally run low or out entirely of controlled

substances. [Tr. 464-466]. But, Ms. Lohne testified that RVIHC never completely ran out of hydrocodone during 2010, although she did testify that the dispensary had run low on controlled substances, including having as little as five or seven dosage units on hand. [Tr. 240-241]. Ms. Lohne, however, also testified that RVIHC's dispensary might have run out of controlled substances by the end of some days. [Tr. 242-243].

H. November 29, 2010 Purchase Order

Kimberly Stillwell, a dental sterilization technician at RVIHC, also testified at the hearing. [Tr. 149]. I find her testimony only partially credible. Though called as a witness for Respondent, her testimony suggested that she bore Dr. Medinnus substantial animus from his employment at RVIHC. Her demeanor while testifying was consistent with this animus towards Respondent and was repeatedly demonstrated by her nonresponsive answers or unsolicited comments adverse to Respondent. Therefore, I decline to credit much of her testimony.

On November 29, 2010, Ms. Stillwell prepared a purchasing order to obtain supplies for RVIHC's dental department. [Govt. Exh. 10; Tr. 151]. At the direction of Dr. Medinnus, she included one bottle of hydrocodone and one bottle of APAP with codeine along with other routine dental supplies in the order. [Id.]. Prior to preparing the order, Dr. Medinnus directed Ms. Stillwell to obtain authorization for the purchase order from Mr. Russ, specifically concerning the inclusion of controlled substances in the order. [Tr. 153, 155]. Ms. Stillwell testified that she spoke to Mr. Russ before placing the purchase order. [Tr. 155]. During this conversation, Ms. Stillwell testified that Mr. Russ said he "did not feel it was a good idea" to order controlled substances for the dental department to dispense directly to patients. [Tr.157-158]. Mr. Russ though could not recall the substance of this conversation with Ms. Stillwell at

the hearing. [Tr. 50-51]. Despite Mr. Russ's misgivings, Ms. Stillwell informed Respondent that Mr. Russ had given his permission for the purchase order. [Tr. 158; Resp. Exh. A140].

The purchase order was then ultimately approved by Jan Scribner, the deputy director of RVIHC, who possessed the ability to approve purchase orders in the absence of Mr. Russ. [Govt. Exh. 10; Govt. Exh. 21; Tr. 46]. Ms. Scribner did not realize that the order contained a request to purchase controlled substances. [Govt. Exh. 21]. Nor did Ms. Stillwell inform her that the order contained a request to purchase controlled substances for use in the dental department. [Tr. 164-165]. Ms. Stillwell received the controlled substances from the purchase order on December 7, 2010 [Govt. Exh. 10 at 4; Tr. 48-49, 150]. She stored the bottle of hydrocodone and the bottle of APAP with codeine in a locked cabinet in the dental department and informed Dr. Medinnus of their arrival. [Tr. 169-170, 173].

I. Respondent's Dispensing of Controlled Substances at RVIHC

Dr. Medinnus testified that he began to dispense hydrocodone directly to dental patients beginning on January 18, 2011. [Tr. 418]. Respondent did not dispense any of the APAP with codeine during this period. [Tr. 432]. Respondent testified that he only intended to dispense the hydrocodone on an emergency basis. [Tr. 418; 475-476]. He further testified that he was experiencing serious marital and personal problems during this period of time and that he was under a great deal of personal and professional stress due to the absence of dental department employees and the hospitalization of his mother-in-law. [Tr. 436-437; Resp. Exh. A117, A123, A138]. Ms. Stillwell testified that she never saw Dr. Medinnus self-abuse any of the hydrocodone kept in the dental department. [Tr. 179-180].

Dr. Medinnus did acknowledge that he did not keep a separate dispensing log for hydrocodone that he dispensed during this period. [Tr. 491; Govt. Exhs. 18, 19]. Instead, he

notated the dispensing of hydrocodone in each patient's dental chart. [Tr. 68; Govt. Exh. 13]. He testified that by not keeping a separate dispensing log, he violated the conditions of his DBC probation. [Tr. 509].

Respondent also testified that he dispensed hydrocodone to one patient, a transient named "JC", without recording it in the patient's chart. [Tr. 519-525]. Again, due to concerns about the bias she displayed during her testimony and her lack of recall regarding this specific patient, I decline to credit Ms. Stillwell's account of the dispensing of hydrocodone to this patient. [Tr. 178, 180-184]. Dr. Medinnus credibly testified that he had examined the patient on January 20, 2011, and observed that he needed a surgical extraction on two of his teeth. [Tr. 421, 521-22]. When the patient returned to RVIHC on January 24, 2011, Dr. Medinnus could not perform the extraction because of his busy schedule. [Id.: Tr. 523]. When the patient reported experiencing pain symptoms, Dr. Medinnus agreed to provide him with hydrocodone to temporarily alleviate his symptoms. [Tr. 421-22, 522-523]. Although Ms. Stillwell offered to retrieve the patient's chart to record the dispensing, Dr. Medinnus testified that due to the clinic's busy schedule, he did not receive the patient chart and thus he did not record the dispensing of hydrocodone to this patient in the chart. [Tr. 422, 523-525].

The Respondent accepted responsibility for his failure to document this dispensing to "JC". [Tr. 523]. Further, the Respondent offered to stipulate to the audit numbers' discrepancy, concluding that "[r]egardless, of course, the fault for this confusion is mine alone." [Resp. Brief at 7; see also Tr. 539-40; Govt. Exh. 19; ALJ Exh. 6].

J. Discovery of Respondent's Dispensing of Controlled Substances

On December 14, 2010, independent pharmacy consultant, Tom Reidenbach, performed a quarterly drug utilization audit for RVIHC. [Tr. 53-54; Govt. Exh. 15]. In that report, he wrote

that "I recommended to Dr. Medinnus that all controlled substances continue to be dispensed from the dispensary." [Govt. Exh. 15 at 2].

On January 27, 2011, Mr. Reidenbach conducted a chart audit related to the dispensing of hydrocodone. In his report, Mr. Reidenbach noted that there "were several deficiencies in the dental clinic record keeping. There were 3 prescriptions that did not have chart orders evident. There were also 9 chart orders that were not dispensed from the dispensary. These were all after 1/20/11."

After receiving Mr. Reidenbach's report, Mr. Russ attended a meeting on January 28, 2011, with RVIHC staff to discuss Mr. Reidenbach's findings. [Tr. 59-62, 82-84]. During this meeting, a RVIHC staff member observed that the dispensary had experienced a dramatic decline in orders for hydrocodone from the dental department. [Tr. 61-63]. Ms. Lohne, who was also at this meeting, had observed a similar gap in the patient orders for controlled substances from the dental department. [Tr. 193].

At the conclusion of this meeting, Mr. Russ went to Dr. Medinnus' office and asked him if he had any hydrocodone in his office. [Tr. 63]. Respondent acknowledged that he had a bottle of hydrocodone in the dental office and he informed Mr. Russ that RVIHC management had approved the purchase order containing the hydrocodone bottle. [Id.]. Mr. Russ instructed Dr. Medinnus to take the hydrocodone bottle to the dispensary. [Tr. 65]. That same day, Dr. Medinnus turned over the bottle of hydrocodone and the unopened bottle of APAP with codeine to Ms. Lohne in the dispensary. [Tr. 195-196]. He did not have a dispensing log at that time. [Id.].

One or two days later, Mr. Russ asked Dr. Medinnus if he had kept a dispensing log to track the hydrocodone he had dispensed. [Tr. 66-67]. Respondent said that he had not kept a

dispensing log, so Mr. Russ instructed him to consult the patient charts and recreate a dispensing log to account for the dosage units he had dispensed. [Tr. 68]. Ms. Lohne also directed Dr. Medinnus to prepare a dispensing log for the bottle of hydrocodone. [Tr. 196]. Dr. Medinnus prepared this dispensing log for the hydrocodone he dispensed directly to patients from the dental department, and he provided the log to Ms. Lohne on February 2, 2011. [Govt. Exh. 11; Resp. Exh. A161; Tr. 69, 198-199, 203].

Mr. Russ then directed Ms. Lohne to account for the apparent discrepancies from Respondent's dispensing log to the number of dosage units left in the bottle when Dr. Medinnus turned it in to the dispensary. [Tr. 69-70, 188-189]. Ms. Lohne began by determining that the bottle of hydrocodone originally contained five hundred dosage units when it was ordered from Henry Schein. [Tr. 198]. And when Dr. Medinnus provided the bottle to Ms. Lohne, she and another nurse physically counted the remaining pills and determined there were one hundred and forty dosage units left in the bottle. [Id.]. Then Ms. Lohne conducted a patient chart audit to verify the Respondent's dispensing log and she prepared a document summarizing the result of her review. [Govt. Exh. 12; Tr. 204-212].

Her audit revealed that the dental department patient charts showed that Dr. Medinnus had dispensed three hundred and eighty-eight dosage units of hydrocodone, even though the Respondent's dispensing log showed he only dispensed three hundred and sixty dosage units of hydrocodone. [Govt. Exh. 12; Govt. Exh. 13; 208-211]. Ms. Lohne then crosschecked the patient charts and Respondent's dispensing log with the carbon copy duplicates of the prescription orders for hydrocodone associated with each patient file, which showed that Respondent had only dispensed three hundred and twenty dosage units of hydrocodone. [Govt. Exh. 12; Tr. 206-207]. When Ms. Lohne reviewed the patient charts, she noticed that in some

files, Dr. Medinnus had altered the number of dosage units he had dispensed. [Govt. Exhs. 13, 19-20; Tr. 221-236].

Unwilling to credit the patient files altered by Respondent, Ms. Lohne concluded that RVIHC could not account for approximately forty dosage units of hydrocodone from the bottle that Dr. Medinnus had ordered. [Tr. 237-238]. Thus, on February 4, 2011, RVIHC filed a DEA Form 106, a Report of Theft or Loss of Controlled Substances, for forty hydrocodone tablets. [Govt. Exh. 14; Tr. 238]. Ms. Lohne testified that this figure came from her audit, which showed three hundred and twenty dosage units dispensed from the dental department according to duplicate prescription orders from each patient file and one hundred and forty dosage units remaining in the bottle when it was returned to the dispensary. [Tr. 238; Govt. Exh. 12].

Following this report, Dr. Medinnus offered to report himself to his probation monitor, Shirley Boldrini, at the DBC. [Tr. 109]. On February 9, 2011, Respondent called and sent an email to Ms. Boldrini reporting a violation of his DBC probation. [Govt. Exhs. 18, 19]. That same day, Mr. Russ placed Dr. Medinnus on a thirty-day suspension. [Tr. 109-110, 145; Resp. Exh. 4 at 24]. Respondent offered to perform a number of conditions during this suspension, including weekly drug testing, weekly therapy and AA meetings, and taking continuing dental education courses. [Tr. 97-99; Govt. Exh. 18]. Mr. Russ did not agree to these conditions. [Tr. 91]. However, during his suspension, Dr. Medinnus notified Ms. Boldrini that he was completing these self-imposed conditions. [Resp. Exh. A125 at 1, 2, 11, and 17].

The record also contains an email dated February 11, 2011, from the RVIHC psychologist, Dr. Mack, who had been treating the Respondent since the Fall of 2010. He concluded that "the recent documentation error [by the Respondent] was the result of acute stress and fatigue and not an attempt to be deceitful or abuse the medication." [Resp. Exh. A123].

On March 10, 2011, Dr. Medinnus resigned from RVIHC. [Resp. Exh. A126; Govt. Exh. 17].

K. DBC and DEA Investigation of Respondent

Geno Davis, a DBC investigator, also testified at the hearing. [Tr. 286]. I find his testimony credible and consistent with the documentary evidence. Mr. Davis serves as Respondent's current probation monitor for the Board. [Tr. 288]. When the Board was notified of a potential narcotic or drug discrepancy involving Dr. Medinnus while he was employed at RVIHC, Mr. Davis was assigned to be Respondent's probation monitor. [Tr. 289]. Mr. Davis interviewed Respondent at the Board's office in Sacramento, California in August 2011. [Tr. 294-295]. When asked about the discrepancies in Respondent's dispensing log for the hydrocodone, Dr. Medinnus told Mr. Davis that he had poured the hydrocodone tablets into a small envelope before giving it to each patient, which may have accounted for the discrepancies in the patient charts and his dispensing log because he may have inadvertently dispensed more tablets than he had intended. [Tr. 295-297].

Following this interview, Mr. Davis contacted the Respondent by phone and asked him if he had personally taken any of the hydrocodone. [Tr. 298]. Dr. Medinnus denied taking any of the hydrocodone. [Id.]. Mr. Davis further testified that Respondent had taken drug-screening tests at the direction of the Board in 2011 and that all of his tests were negative. [Tr. 315; Resp. Exh. A128]. Lastly, Mr. Davis testified that the Board has filed an accusation against Respondent with the California Attorney General's Office regarding the lack of documentation in a dispensing log, and that the accusation is currently pending with that office. [Tr. 316-317].

DEA Diversion Investigator Craig Tom also testified at the hearing. [Tr. 318 - 319]. I find his testimony credible and consistent with the documentary evidence. DI Tom was assigned

to investigate Respondent's application for registration. [Tr. 320]. DI Tom coordinated his investigation with the DBC and also spoke with Mr. Russ regarding the Respondent's conduct at RVIHC. [Tr. 332-333]. DI Tom testified that Dr. Medinnus was truthful in the applications for registration that he submitted to the DEA. [Tr. 333]. DI Tom did not interview Dr. Medinnus. [Id.].

L. Respondent's Current Situation

Dr. Medinnus currently possesses an active California dental license, subject to the probationary conditions imposed by the DBC's June 12, 2007 order. He is currently employed as a dentist at the ANAV Tribal Health Clinic in Fort Jones, California, where he has worked since April 21, 2011. [Resp. Exh. A129; Tr. 541]. Dr. Medinnus has not dispensed or prescribed any controlled substances while working at the ANAV Tribal Health Clinic. [Tr. 545]. Respondent credibly testified that obtaining a DEA registration may be necessary for him to continue at his present position and to be eligible to become the dental director. [Tr. 547-548]. In addition, Respondent proffered two letters of recommendation regarding his application for a DEA Registration from his supervisors at the ANAV Tribal Health Clinic. [Resp. Exh. A151-152]. The ANAV Tribal Health Clinic does not store or dispense any narcotic medications and only faxes the prescriptions to neighboring pharmacies. [Id.].

IV. STATEMENT OF LAW AND DISCUSSION

A. Position of the Parties

1. Government's Position

The Government asserts that the appropriate remedy in this matter is denial of the Respondent's application. [Govt. Brief at 25-26]. First, the Government argues that by procuring the order of the bottle of hydrocodone and then subsequently surreptitiously

dispensing it to dental patients, Respondent violated federal law, the terms of his DBC probation and his RVIHC contract. [Id. at 20-21]. Next, the Government cites Respondent's failure to maintain accurate dispensing records as further evidence of his unfitness to possess a DEA Registration. [Id. at 23-24]. Lastly, the Government cites Agency precedent and argues that Respondent's lack of candor at the hearing and his inability to accept responsibility for his conduct also supports the denial of Respondent's application. [Id. at 21-23].

The Government makes several arguments to justify the denial of Respondent's application. Primarily, the Government argues that Respondent violated federal law and his DBC probation by failing to maintain a contemporaneous dispensing log for the hydrocodone he dispensed to patients. [Id. at 20, 25]. Similarly, the Government contends that Respondent demonstrated his inability to comply with DEA recordkeeping requirements because he could not even recreate an accurate dispensing log from his own patient records. [Id. at 22, 24-25]. And the Government also highlighted Respondent's failure to record in the patient chart the dispensing of hydrocodone to one of his patients, "JC". [Id. at 23]. In addition, the Government strenuously argues that Respondent has not accepted responsibility or shown any remorse for his conduct. [Id. at 21-23]. Instead, the Government argues that Respondent has "downplayed, indeed mischaracterized, his violations" and "has not been truthful as to what really happened." [Id. at 21]. Nor, the Government contends, was Respondent candid with RVIHC personnel regarding his ordering and usage of hydrocodone in the dental department. [Id. at 22-23].

In conclusion, the Government argues that Respondent's application for a DEA Certificate of Registration as practitioner is inconsistent with the public interest and that his application should be denied. [Id. at 25-26].

2. Respondent's Position

Respondent asserts that the appropriate remedy in this matter is the conditional granting of his application. [Resp. Brief at 34-35]. First, Dr. Medinnus acknowledges his misconduct in not maintaining the required dispensing log at RVIHC pursuant to his DBC probation. [Id. at 7-8, 20]. In mitigation, Respondent describes in detail the "profound personal and professional hardship" that he experienced during his employment at RVIHC. [Id. at 10-11, 20]. Respondent further notes that he self-reported his violations to the DBC and also fully disclosed the incident on his DEA application. [Id. at 20]. Respondent also argues that he has consistently taken responsibility for this misconduct, including in his testimony at the hearing. [Id. at 8-10, 20]. In addition, Dr. Medinnus argues that the record contains no evidence of self-abuse or diversion of controlled substances during his employment at RVIHC. [Id. at 9-10, 20].

Next, Respondent argues that the Government has failed to prove its allegations that he made an unauthorized purchase of hydrocodone or that he violated RVIHC's policies on storing and dispensing by directly dispensing to patients in the dental department. [Id. at 20-33].

Respondent's primary claim is that Mr. Russ verbally authorized the November 29, 2011 purchase order, which rendered Respondent's subsequent storing and dispensing of the hydrocodone compliant with RVIHC's policy. [Id. at 26-31]. To this point, Respondent meticulously details RVIHC's changing policy on the dispensing of controlled substances during late 2010 and early 2011 and the problems that the dispensary had in maintaining adequate supplies of controlled substances. [Id. at 21-26]. Dr. Medinnus also argues that these allegations concerning the purchase and dispensing of hydrocodone were never disclosed to him or discussed with him until the DEA initiated the Order to Show Cause proceedings. [Id. at 31-33].

Lastly, Respondent argues that denying his application for registration would be a disproportionate penalty for his conduct at RVIHC. [Id. at 20, 34]. Therefore, in light of Respondent's acceptance of responsibility, Respondent argues that granting his application for a restricted registration would be consistent with the public interest. [Id. at 34-35]. He recommends that his registration be subject to several conditions, including complying with the terms of his California dental license probation, being limited to only prescribing controlled substances and not administering, ordering, or dispensing them, being prohibited from prescribing controlled substances to himself or any family members, and maintaining a log of all controlled substances prescriptions he authorizes and providing this log to the local DEA office on a quarterly basis. [Id.].

B. Statement of Law and Analysis

Pursuant to 21 U.S.C. § 823(f) (2006),¹ the Deputy Administrator may deny an application for a DEA Certificate of Registration if he determines that such registration would be inconsistent with the public interest. In determining the public interest, the following factors are considered:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

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¹ The Deputy Administrator has the authority to make such a determination pursuant to 28 C.F.R. §§ 0.100(b), 0.104 (2012).

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f) (2006).

These factors are to be considered in the disjunctive; the Deputy Administrator may rely on any one or a combination of factors and may give each factor the weight he deems appropriate in determining whether a registration should be revoked. See Robert A. Leslie, M.D., 68 Fed. Reg. 15,227, 15,230 (DEA 2003). Moreover, the Deputy Administrator is "not required to make findings as to all of the factors." Hoxie v. DEA, 419 F.3d 477, 482 (6th Cir. 2005); see also Morall v. DEA, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

The Government bears the ultimate burden of proving that the requirements for registration are not satisfied. 21 C.F.R. § 1301.44(d) (2012). However, where the Government has made out a <u>prima facie</u> case that Respondent's application would be "inconsistent with the public interest," the burden of production shifts to the applicant to "present[] sufficient mitigating evidence" to show why he can be entrusted with a new registration. <u>See Medicine Shoppe—Jonesborough</u>, 73 Fed. Reg. 364, 387 (DEA 2008). To this point, the Agency has repeatedly held that the "registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct." <u>Medicine Shoppe--Jonesborough</u>, 73 Fed. Reg. at 387; <u>see also Samuel S. Jackson, D.D.S.</u>, 72 Fed. Reg. 23,848, 23,853 (DEA 2007). In short, after the Government makes its <u>prima facie</u> case, the Respondent must produce sufficient evidence that he can be entrusted with the authority that a registration provides by demonstrating that he accepts responsibility for his misconduct and that the misconduct will not reoccur.

1. Factor One: Recommendation of Appropriate State Licensing Board

Although the recommendation of the applicable state licensing board is probative to this factor, the Agency possesses "a separate oversight responsibility with respect to the handling of

controlled substances" and therefore must make an "independent determination as to whether the granting of [a registration] would be in the public interest." Mortimer B. Levin, D.O., 55 Fed.

Reg. 8,209, 8,210 (DEA 1990); see also Jayam Krishna-Iyer, M.D., 74 Fed. Reg. 459, 461 (DEA 2009). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. Edmund Chein, M.D., 72 Fed. Reg. 6,580, 6,590 (DEA 2007), aff'd, Chein v.

DEA, 533 F.3d 828 (D.C. Cir. 2008). So while not dispositive, state board recommendations are relevant on the issue of revoking or maintaining a DEA registration. See Gregory D. Owens, D.D.S., 74 Fed. Reg. 36,751, 36,755 (DEA 2009); Martha Hernandez, M.D., 62 Fed.

Reg. 61,145, 61,147 (DEA 1997).

In this case, the DBC has not made a specific recommendation concerning the granting of a DEA registration to the Respondent. The DBC has reinstated Respondent's dental license, subject to a series of probationary conditions. [Govt. Exh. 7, 8; Tr. 330-331]. Thus, Dr. Medinnus currently possesses an active dental license in the state of California. [Id.]. Nevertheless, the Agency has consistently held that a practitioner's possession of state authority, while a prerequisite to seeking a registration, is not dispositive of the public interest determination. Mark De La Lama, P.A., 76 Fed. Reg. 20,011, 20,018 (DEA 2011). Therefore, I find that this factor does not weigh in favor or against the granting of Respondent's application for a DEA Certificate of Registration.

2. <u>Factor Three: Applicant's Conviction Record Relating to Controlled</u> Substances

The record contains evidence that the Respondent has been convicted of an offense related to the manufacture, distribution or dispensing of controlled substances, namely his 2003 felony conviction for violating CAL. HEALTH & SAFETY CODE § 11173(a) (West 2012) for

obtaining controlled substances by fraud. [Resp. Exh. 3]. Thus, I find that this factor weighs against the granting of Respondent's application for a DEA Certificate of Registration. Scott H. Nearing, 70 Fed. Reg. 33,200, 33,202 (DEA 2005).

3. <u>Factor Five: Such Other Conduct Which May Threaten the Public Health and Safety</u>

The Agency has long held that a practitioner's self-abuse of controlled substances constitutes "conduct which may threaten public health and safety." 21 U.S.C. § 823(f)(5) (2006); see also Tony T. Bui, M.D., 75 Fed. Reg. 49,979, 49,990 (DEA 2010); Kenneth Wayne Green, Jr., M.D., 59 Fed. Reg. 51,453 (DEA 1994); David E. Trawick, D.D.S., 53 Fed. Reg. 5,326 (DEA 1988). Here, the Respondent self-abused and diverted to his family members significant quantities of hydrocodone, lorazepam, and diazepam from approximately January 2000 through November 2001. [Govt. Exhs. 5, 6, and 7]. Such unlawful ingestion and diversion of controlled substances clearly places the public health and safety in jeopardy. This unlawful conduct led to the surrender of Respondent's California dental license and initial DEA registration.

Yet, I find that the Respondent has successfully addressed his addiction problem and returned to the practice of dentistry by regaining his dental license in 2007. At the hearing, Dr. Medinnus proffered substantial and detailed evidence regarding his impressive recovery program, including numerous negative drug screens he has taken over the past nine years. [Resp. Brief at 2-7, 9-10]. As the Deputy Administrator has previously determined, "[t]he paramount issue is not how much time has elapsed since [the Respondent's] unlawful conduct, but rather, whether during that time [the] Respondent has learned from past mistakes and has demonstrated that he would handle controlled substances properly if entrusted with a DEA registration."

Leonardo V. Lopez, M.D., 54 Fed. Reg. 36,915 (DEA 1989). Even though it has been

previously found that time, alone, is not dispositive in such situations, it is certainly an appropriate factor to be considered. See Robert G. Hallermeier, M.D., 62 Fed. Reg. 26,818 (DEA 1997) (four years); John Porter Richards, D.O., 61 Fed. Reg. 13,878 (DEA 1996) (ten years); Norman Alpert, M.D., 58 Fed. Reg. 67,420, 67,421 (DEA 1993) (seven years). In this case, Respondent has conclusively demonstrated his strong recovery from his previous addiction and his successful maintenance of his sobriety for the past nine years. Therefore, I find that Respondent's history of substance abuse does not weigh against the granting of Respondent's application for a DEA Certificate of Registration.

4. Factors Two and Four: Applicant's Experience With Controlled Substances And Compliance With Applicable State, Federal, Or Local Laws Relating To Controlled Substances

Under the Controlled Substances Act ("CSA" or "the Act") and Agency regulations, it is fundamental that a practitioner who directly dispenses controlled substances maintain an effective recordkeeping system. This includes maintaining inventories and other records pursuant to 21 U.S.C. § 827(a) (2006). They are also required to hold a DEA registration at any location where they dispense controlled substances, see 21 C.F.R. § 1301.12 (2012), and to store controlled substances "in a securely locked, substantially constructed cabinet," id. § 1301.75.

Lastly, practitioners who provide controlled substances directly to patients must maintain written records of such dispensing covering a minimum of two years; take an initial inventory of all controlled substances on hand and biennial inventories thereafter; and maintain records of receipts, dispensings, and transfers of controlled substances. See id. §§ 1304.03(b), 1304.04, 1304.21, 1304.22(c); see also Shawn M. Gallegos, D.D.S., 76 Fed. Reg. 66,986 (DEA 2011).

The Government brought three primary allegations to support the denial of Respondent's application, the unauthorized purchase order for the controlled substances, Respondent's failure to abide by RVIHC's storing and dispensing policies for controlled substances, and his failure to maintain the required dispensing log for the hydrocodone pursuant to his DBC probation. I decline to credit the Government's first two allegations although I find that the Government has met its burden of proof concerning Respondent's failure to maintain the required dispensing log pursuant to his DBC probation and Agency regulations.

First, with regards to the unauthorized purchase allegation, I find that the Government has not sustained its burden of proof. The testimony and evidence elicited at the hearing regarding this purchase order does not support the Government's claim that Respondent was unauthorized to place the order. Dr. Medinnus credibily maintained that Ms. Stillwell told him that Mr. Russ approved the order. [Tr. 158; Resp. Exh. A140; Resp. Brief at 28-31]. As explained above, I decline to credit much of Ms. Stillwell's testimony on her conversation with Mr. Russ regarding this order. Furthermore, I also note that Mr. Russ failed to recall many of the details surrounding this particular order including any conversation he had with Ms. Stillwell prior to the submission of the order to Ms. Scribner. Thus, the evidence in the record does not support a conclusion by a preponderance of the evidence that Dr. Medinnus was responsible for knowingly submitting an unauthorized purchase order for controlled substances. More tellingly, the submission of the purchase order on behalf of the dental department and its subsequent approval by Jan Scribner, a duly authorized RVIHC representative who had the power to approve such orders, appears to belie any contention that the order itself was unauthorized by RVIHC management. While it is likely that RVIHC management, including Mr. Russ and Ms. Lohne, failed to remember that Dr. Medinnus had obtained a bottle of hydrocodone for

emergency use, I conclude that the record does not show that the placement of the November 29, 2010 purchase order was unauthorized.

And as the Respondent persuasively argues, if Dr. Medinnus reasonably believed the purchase order was duly approved, the Government's allegation that he failed to abide by RVIHC policies regarding the storage and dispensing of controlled substances, also fails. [Resp. Brief at 20-21]. While the Government has elicited substantial testimony and evidence regarding RVIHC's policies and procedures related to dispensing controlled substances, it has failed to link these policies to any deliberate or knowing attempt on behalf of the Respondent to violate them. [Govt. Brief at 21-22]. Indeed, when Mr. Russ confronted Dr. Medinnus regarding the bottle of hydrocdone, Respondent promptly admitted to ordering and storing the controlled substances and pointed to the approval of the purchase order as justification for his conduct. [Tr. 63]. Such a response supports Respondent's consistent position that he honestly and reasonably believed he possessed the necessary authority to store and dispense controlled substances in the dental department. Therefore, I decline to credit the Government's allegation that Respondent violated RVIHC's policies on the storage and dispensing of controlled substances.

Both parties however, do acknowledge that Dr. Medinnus failed to maintain the required dispensing log for these controlled substances. [Resp. Brief at 7-8; Govt. Brief at 20]. In addition, I find that Dr. Medinnus failed to properly chart each dispensing of hydrocodone he gave to a patient, most notably with regards to his dispensing to "JC", which represents another serious violation of Agency recordkeeping regulations. Nor was Respondent's clumsy attempt to reconstruct a dispensing log and alteration of patient charts consistent with a registrant's duty to maintain complete and accurate records regarding controlled substances. Therefore, I find that Respondent committed several serious violations of the Act's recordkeeping requirement,

Agency regulations, as well as the terms of his DBC probation. Thus, in light of Respondent's serious and undisputed violations of the CSA's recordkeeping requirements and his DBC probation, I conclude that the Government has presented a <u>prima facie</u> case that supports the denial of Respondent's application.

After the Government "has proved that a registrant has committed acts inconsistent with the public interest, a registrant must 'present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration."

Medicine Shoppe--Jonesborough, 73 Fed. Reg. 364, 387 (DEA 2008) (quoting Samuel S.

Jackson, D.D.S., 72 Fed. Reg. 23,848, 23,853 (DEA 2007). "Moreover, because 'past performance is the best predictor of future performance,' Alra Labs., Inc. v. DEA, 54 F.3d 450, 452 (7th Cir. 1995), "[DEA] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for his actions and demonstrate that he will not engage in future misconduct." Medicine Shoppe--Jonesborough, 73 Fed. Reg. at 387; see also Samuel S. Jackson, D.D.S., 72 Fed. Reg. 23, 848, 23,853 (DEA 2007); Hoxie v. DEA, 419 F.3d 477, 483 (6th Cir. 2005) ("admitting fault" is "properly consider[ed]" by DEA to be an "important factor[]" in the public interest determination).

Here, I find that Respondent has both taken responsibility for his actions and shown remorse for his conduct. During his testimony, Dr. Medinnus repeatedly demonstrated remorse for his conduct at the RVIHC. He also testified credibly and candidly about the circumstances surrounding the misconduct, including the various personal and professional challenges he faced during his employment at RVIHC.

The Government argues that the Respondent attempted to "minimize" his misconduct by testifying that he could only not account for forty dosage units of the hydrocodone. [Govt. Brief

at 22]. I disagree. Instead, I find that while this evidence, along with the evidence regarding the circumstances surrounding Respondent's employment at RVIHC does not excuse Respondent's conduct, it does provide appropriate mitigating factors for this Court and the Deputy Administrator to consider. See Martha Hernandez, M.D., 62 Fed. Reg. 61,145 (DEA 1997) (holding that, in exercising his discretion in determining the appropriate remedy, the Administrator should consider all of the facts and circumstances of a particular case).

In light of the substantial evidence that Respondent proffered regarding his acceptance of responsibility for the misconduct, I find that the Government's proposed sanction, the denial of Respondent's application, is too severe. As this Agency has repeatedly held, a proceeding under the Act "is a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused . . . their DEA Certificate of Registration, and who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility carried by such a registration." Jon Karl Dively, D.D.S., 72 Fed. Reg. 74,332, 74,334 (DEA 2007) (quoting Samuel S. Jackson, D.D.S., 72 Fed. Reg. 23,848, 23,853 (DEA 2007)). Despite the Government's strenuous arguments to the contrary, I find that Dr. Medinnus' restricted registration does not represent a danger to the public interest. Indeed, Dr. Medinnus has sensibly requested the issuance of a restricted registration, which would ensure that he avoid any repeat of the recordkeeping violations he committed while at RVIHC. While his misconduct was indeed serious, Dr. Medinnus has now demonstrated that he understands the responsibilities and requirements of a DEA registrant.

V. <u>CONCLUSION AND RECOMMENDATION</u>

Therefore, I conclude that the DEA has met its burden of proof and has established that grounds exist for denying the Respondent's application for a DEA Certificate of Registration. I do not condone nor minimize the seriousness of the Respondent's misconduct. However, based on this record, I recommend that the Respondent be afforded an opportunity to demonstrate that he can again responsibly handle controlled substance prescriptions by the granting of a restricted registration. See Cecil E. Oakes, Jr., M.D., 63 Fed. Reg. 11,907, 11,910 (DEA 1998) ("Such a resolution will provide Respondent with the opportunity to demonstrate that he can responsibly handle controlled substances, while at the same time protect the public health and safety, by providing a mechanism for rapid detection of any improper activity."). The Agency has previously held that "such restrictions must be related to what the Government has alleged and proved in any case." Janet L. Thornton, D.O., 73 Fed. Reg. 50,354, 50,356 (DEA 2008).

Consistently, I suggest that the conditions in this case be tailored to ensure that the Respondent does not personally handle or dispense controlled substances. Thus, they should include: that the registration restricts his handling of controlled substances to merely prescribing and not storing, administering or dispensing such drugs and that he be prohibited from prescribing controlled substances to himself or any family member. Further, I recommend that the Respondent be ordered to comply with the terms of his DBC probation and promptly notify the DEA if the DBC takes any action against his dental license. Lastly, I recommend that he maintain and provide quarterly prescription logs for all controlled substances prescriptions he authorizes to the local DEA office for monitoring. I recommend these restrictions apply for three

years from the date of the final order so directing this result. In this way, the Respondent may

safely continue his return to the full practice of dentistry, and the DEA can assure itself of the

Respondent's compliance with DEA regulations as well as the protection of the public interest.

Date: October 17, 2012

s/Gail A. Randall

Administrative Law Judge

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